

DEC 23 1996

K962138

## 510(k) Summary

### SUMMARY OF SAFETY AND EFFECTIVENESS

1. **Model Name:** MRT-50GP/E2 and MRT-50GP/H1  
**Device Name:** Magnetic Resonance Device  
**Trade/Proprietary Name:** FLEXART™ V3.1
2. **Establishment Registration:** #2936923
3. **U.S. Agent Name and Address:** TOSHIBA AMERICA MRI, INC.  
280 Utah Ave.  
South San Francisco, CA 94080

**Contact Person:** Steven M. Kay  
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4. **Manufacturing Site:** Toshiba Corporation  
1385 Shimoishigami  
Otawara-shi, Tochigi-Ken  
Japan 324

5. **DATE OF SUBMISSION:** May 30 1996

#### 6. DEVICE DESCRIPTION

Version 3.1 software consists of two model upgrades to the FLEXART™ system. The MRT-50GP/E2 (Flexart™) includes such new applicational features as FastASE, QuadScan and MR Fluoroscopy for scanning and MSOFT and PASTA for fat suppression. The MRT-50GP/H1 (Flexart™/Hyper) increases the gradient field strength over that of the Flexart™.

#### 7. SAFETY PARAMETERS

	<u>MRT-50GP</u>	<u>MRT-50GP/E2</u>	<u>MRT-50G/H1</u>
Maximum static field strength:	0.5 T	Same	Same
Rate of change of magnetic field ( $\tau = 1000\text{ms}$ ):	11 T/sec,	Same	13.3 T/sec.
Max. Radio frequency power deposition:	<0.256 W/kg	Same	<0.34 W/kg
Acoustic Noise levels:	100.2 dB (A) (Maximum)	Same (Maximum)	98.5 dB (A) (Maximum)

Acoustic noise data was measured in accordance with NEMA guidelines. The user is cautioned to have the patient wear acoustic noise protection during scanning, thus ensuring that the patient observed noise level is significantly below 100 dB (A).

# 510(k) Summary (cont'd)

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### 8. IMAGING PERFORMANCE PARAMETERS

		<u>MRT-150A</u>	<u>MRT-150/H1</u>	<u>MRT-150/F1</u>
Specification volume:	Head:	10.4 cm dsv	14 cm dsv	14 cm dsv
	Body:	10.4 cm dsv	28 cm dsv	28 cm dsv

Sample phantom images and clinical images were presented for all new sequences, demonstrating conformance with consensus standards requirements for Signal-to-Noise ratio, Uniformity, Slice Profiles, Geometric Distortion and Slice Thickness/Interslice Spacing.

### 9. INTENDED USE

Anatomical Region: Head, Body, Extremity, Spine, Neck, TMJ, and Heart  
Nuclei excited: Hydrogen  
Diagnostic Use: Imaging of the whole body (including the head, abdomen, heart, pelvis, spine, blood vessels, limbs and extremities), fluid visualization, 2D/3D Imaging, MR Angiography, MR. Fluoroscopy.

### 10. EQUIVALENCY INFORMATION

Toshiba America Medical Systems, Inc. (TAMS) believes the FLEXART™ and FLEXART™/HYPER systems with V3.1 are substantially equivalent to the MRT-50GP FLEXART™ because they consist of hardware and software upgrades that improve the performance of the basic FLEXART™, without introducing new questions of safety or efficacy. The FLEXART™ was cleared by K933018. The increased gradient field strength is less than the IEC standard and that of other manufacturers systems currently on the market. New surface coils for this system received prior market clearance from the Agency. Software upgrades provide for improved image quality, but do not change the intended uses of the device. MR Fluoroscopy is similar to the same function that was cleared for the MRT-35A. Good Manufacturing Practices requirements are unchanged from those already in effect for the FLEXART™.